AO88 (Rev. 12/06) Subpoena in a Civil Case

Issued by the

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

Louisiana Wholesale Drug Company, Inc.

V.

Sanofi-Aventis, Sanofi-Aventis U.S. LLC, and Aventis Pharmaceuticals, Inc.

SUBPOENA IN A CIVIL CASE

Case Number:[1] 07-CIV-7343

TO: *Kali Laboratories, Inc.
Thomas Haughey
C/O Par Pharmaceuticals
300 Tice Boulevard, Woodcliff Lake, NJ 07677

☐ YOU ARE COMMANDED to appear in the United States District court at the place, date, and time specified below to testify in the above case.

PLACE OF TESTIMONY	COURTROOM
	DATE AND TIME

☑ YOU ARE COMMANDED to appear at the place, date, and time specified below to testify at the taking of a deposition in the above case.

PLACE OF DEPOSITION	DATE AND TIME
Garwin Gerstein & Fisher, LLP, 1501 Broadway, New York, NY 10036	11/29/2007 9:00 am

☑ YOU ARE COMMANDED to produce and permit inspection and copying of the following documents or objects at the place, date, and time specified below (list documents or objects):

Please see attached Schedule "A"

PLACE	DATE AND TIME
Kozyak Tropin & Throckmorton, P.A., 9th Floor, 2525 Ponce de Leon, Miami, Florida, 33134	11/19/2007 5:00 pm

☐ YOU ARE COMMANDED to permit inspection of the following premises at the date and time specified below.

PREMISES	DATE AND TIME

Any organization not a party to this suit that is subpoenaed for the taking of a deposition shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. Federal Rules of Civil Procedure, 30(b)(6).

ISSUING OFFICER'S SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFENDANT)	DATE
	10/19/07

ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER

Thomas A. Tucker Ronzetti, Esq.
Kozyak Tropin & Throckmorton, P.A., 9th Floor, 2525 Ponce de Leon, Miami, Florida, 33134; (Phone) 305-372-1800

(See Rule 45, Federal Rules of Civil Procedure, Subdivisions (c), (d), and (e), on next page)

[1] If action is pending in district other than district of issuance, state district under case number.

*The deponent shall be, pursuant to FRCP 30(b)(6), the corporate representative with the most knowledge of the matters identified in Scedule "A".

PROOF OF SERVICE

DATE PLACE

SERVED

SERVED ON (PRINT NAME) MANNER OF SERVICE

SERVED BY (PRINT NAME) TITLE

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on _____ _____
DATE SIGNATURE OF SERVER

ADDRESS OF SERVER

Rule 45, Federal Rules of Civil Procedure, Subdivisions (c), (d), and (e), as amended on December 1, 2006:

(c) PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction, which may include, but is not limited to, lost earnings and a reasonable attorney's fee.

(2) (A) A person commanded to produce and permit inspection, copying, testing, or sampling of designated electronically stored information, books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial.

(B) Subject to paragraph (d)(2) of this rule, a person commanded to produce and permit inspection, copying, testing, or sampling may, within 14 days after service of the subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to producing any or all of the designated materials or inspection of the premises — or to producing electronically stored information in the form or forms requested. If objection is made, the party serving the subpoena shall not be entitled to inspect, copy, test, or sample the materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production, inspection, copying, testing, or sampling. Such an order to compel shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection, copying, testing, or sampling commanded.

(3) (A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it

(i) fails to allow reasonable time for compliance;

(ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c)(3)(B)(iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held;

(iii) requires disclosure of privileged or other protected matter and no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) If a subpoena

(i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or

(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or

(iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena or, if the party in whose behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

(d) DUTIES IN RESPONDING TO SUBPOENA.

(1) (A) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.

(B) If a subpoena does not specify the form or forms for producing electronically stored information, a person responding to a subpoena must produce the information in a form or forms in which the person ordinarily maintains it or in a form or forms that are reasonably usable.

(C) A person responding to a subpoena need not produce the same electronically stored information in more than one form.

(D) A person responding to a subpoena need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or to quash, the person from whom discovery is sought must show that the information sought is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) (A) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial-preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

(B) If information is produced in response to a subpoena that is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has and may not use or disclose the information until the claim is resolved. A receiving party may promptly present the information to the court under seal for a determination of the claim. If the receiving party disclosed the information before being notified, it must take reasonable steps to retrieve it. The person who produced the information must preserve the information until the claim is resolved.

(e) CONTEMPT. Failure of any person without adequate excuse to obey a subpoena served upon that person may be deemed a contempt of the court from which the subpoena issued. An adequate cause for failure to obey exists when a subpoena purports to require a nonparty to attend or produce at a place not within the limits provided by clause (ii) of subparagraph (c)(3)(A).

SCHEDULE "A"

I. DEFINITIONS

1. The term "person" means a natural person, corporation, association, company, firm, partnership, joint venture, trust, estate, agency, department or bureau, governmental or judicial person or legal entity.

2. The term "Aventis" shall mean, unless otherwise specified in a particular request, Sanofi-Aventis, Sanofi-Aventis U.S. LLC, and Aventis Pharmaceuticals, Inc., their predecessor and successor entities, their officers, directors, shareholders, parent and subsidiary companies (where direct or indirect), employees, agents, attorneys, representatives and other persons acting or authorized to act on behalf of Sanofi-Aventis, Sanofi-Aventis U.S. LLC, and Aventis Pharmaceuticals, Inc.

3. The term "Arava" means any and all drugs or pharmaceutical products which are, or have in the past been, marketed, sold or labeled under the trademark or name "Arava," regardless of the form, formulation, strength, dosage, dissolution rate or package size of the drugs, including but not limited to the pharmaceutical product described in the New Drug Application 20-0905.

4. The term "leflunomide" means any and all products, drugs or pharmaceuticals, regardless of the form, formulation, strength, dosage, dissolution rate or package size of the drugs, which contain the chemical or compound leflunomide as an active ingredient or product, including, but not limited to, Arava and its AB-rated generics

5. The term "FDA" refers to the United States Food and Drug Administration,

including any of its departments, committees, subdivisions or individuals or entities acting on its behalf or under its authority.

6. The terms "generic," "generically equivalent," or "generic drug equivalent" means a pharmaceutical product or drug product which has been submitted to, or deemed by, the FDA as meeting necessary requirements to be an AB-rated alternative to a branded product, as such is defined by the FDA.

7. The terms "you", "your" or "yours" shall mean Kali Laboratories, Inc., in any and all legal forms, its predecessor and successor entities, officers, directors, shareholders, parent and subsidiary companies (where direct or indirect), employees, agents, attorneys, representatives and other persons acting or authorized to act on behalf of Kali Laboratories, Inc.

8. The term "loading dose" means the 100 mg dose per day for three (3) days recommended when an individual is started on Arava therapy in Arava's FDA-approved labeling.

9. The term "Aventis' Citizen Petition" means the Citizen Petition dated March 31, 2005 (Docket No. 2005P-0127/CP1), and the related Comment, dated June 10, 2005 (2005P-0127/RC1), that Aventis filed, or caused to be filed, with the FDA.

10. The term "document" is synonymous in meaning and equal in scope to the usage of this term in Federal Rules of Civil Procedure, and includes but is not limited to information contained and/or stored in any written, printed, recorded, digital, electronic and or/video matter, computer databases and/or electronic mail. A draft, revision or copy of a document that has any non-conforming notes, marginal annotations or other markings is a separate document within the meaning of this term.

11. The phrase "relating to" and "relates to" includes reflecting, constituting, evidencing, referring to, concerning, involving, dealing with, or bearing on (whether legally, factually, or otherwise), in whole or part.

12. The term "communication" and "communications" include all forms of transmission of information (in the form of facts, ideas, inquiries or otherwise), whether in oral or in writing or in some other medium.

13. The term "correspondence" means any letter, memorandum or other writing.

14. The term "minutes" means any document created in connection with a meeting, including minutes of a meeting, exhibits and attachments to minutes of a meeting, agendas for meetings (including exhibits, attachments and/or materials distributed or circulated at, or in connection with, any meeting), notices of meetings, waivers of meetings and certification or signatures appended to or referred to in the notices, agendas or minutes.

15. The terms "and/or," "or," and "and" are used inclusively, not exclusively.

II. INSTRUCTIONS

1. In producing documents and other materials, you are requested to furnish all documents or things in your possession, custody or control, regardless of whether such documents or materials are possessed directly by you or your directors, officers, agents, employees, representatives, subsidiaries, managing agents, affiliates, investigators or by your attorneys or their agents, employees, representatives or investigators.

2. If any part of a document is responsive to any request, the whole document is to be produced. Any alteration of a responsive document, including any marginal notes,

handwritten notes, underlining, date stamps, received stamps, endorsed or filed stamps, drafts, revisions, modifications and other versions of a final document is a separate and distinct document and it must be produced.

3. If you are unable to produce a document in response to any request, so state and indicate whether the document ever existed, or whether the document once existed but cannot be located. If any document once was, but is no longer in your possession, custody or control, state the whereabouts of any such document when last in your possession, custody or control, state the date and manner of its disposition and identify its last known custodian. To the extent any documents are lost or destroyed, produce any documents which support your assertion that the document was lost or destroyed, and provide the date thereof.

4. If you file a timely objection to any portion of this subpoena, provide a response to the remaining portion.

5. The terms defined above and the individual requests for production and inspection should be construed broadly to the fullest extent of their meaning in a good faith effort to comply with the Federal Rules of Civil Procedure.

6. As used in these requests, the singular shall also be treated as plural and vice-versa.

7. Documents are to be produced in full. Redacted documents will not constitute compliance with this subpoena. If any requested document or thing cannot be produced in full, produce it to the extent possible, indicating which document or portion of that document is being withheld and the reason that document is being withheld.

8. In producing documents, you are requested to produce each document requested

together with all non-identical copies and drafts of that document.

9. All documents created and/or stored in electronic media in the usual course of your business shall be produced in electronic format pursuant to the Instructions herein, in "zipped" files.

10. Where hard copies of documents are responsive to this subpoena, such documents shall be produced in TIFF format together with: (a) an associated, searchable text file, having the same name and located in the same folder; and (b) an Opticon file and IPRO or Summation DII file showing the Bates number of each page and the appropriate unitization of the documents.

11. Where documents comprising electronically-stored information are responsive to a this subpoena, such documents created and/or maintained in the usual course of your business as the following file formats shall be produced in native format:

a. Word (.DOC and all variations)

b. Excel (.XLS and all variations)

c. Adobe Acrobat (.PDF and all variations)

d. HTML (.HTM, .HTML)

e. XML (.XML)

f. WordPerfect (WP, WPD) version 9

g. Standard Text Files (.TXT)

h. Rich Text Files (.RTF)

i. Email (.PST, .EML, .NSF, .MSG)

12. Once produced, each such document shall be accompanied by: (a) an associated, searchable text file, having the same name and located in the same folder; (b) an Opticon file and

IPRO or Summation DII file showing the Bates number of each page and the appropriate unitization of the documents; and (c) all metadata and embedded data associated with the documents.

13. Where documents comprising electronically stored information are responsive to this subpoena, and their native file format is not one listed in the immediately-preceding instruction, pursuant to Federal Rules of Civil Procedure 34(a) and 34(b) you must: (a) identify the native file format to Plaintiffs; and/or (b) provide Plaintiffs will a sample of each such native file format, so that Plaintiffs may determine, and subsequently inform you, prior to production, whether such native format is reasonably useable or, alternatively, what translation by Defendants is required to render the native format reasonably useable. Once produced, each such document shall be accompanied by: (a) an associated, searchable text file, having the same name and located in the same folder; (b) an Opticon file and IPRO or Summation DII file showing the Bates number of each page and the appropriate unitization of the documents; and (c) all metadata and embedded data associated with the documents.

14. All documents shall be produced in the file folder, envelope or other container in which the documents are kept or maintained by you. If, for any reason, the container cannot be produced, produce copies of all labels or other identifying marks.

15. Documents shall be produced in such fashion as to identify the department, branch or office in whose possession it was located and, where applicable, the natural person in whose possession it was found and the business address of each document's custodian(s).

16. Documents attached to each other should not be separated.

17. Documents not otherwise responsive to this subpoena shall be produced if such

documents mention, discuss, refer to or explain the documents which are called for by this subpoena, or if such documents are attached to documents called for by this subpoena and constitute routing slips, transmittal memoranda, letters, comments, evaluations or similar materials.

18. If any documents described herein have been lost, discarded, destroyed, or are otherwise no longer in your possession, custody or control, or have been transferred voluntarily or involuntarily to another person or persons, or otherwise disposed of, they shall be identified as completely as possible including, but not limited to, information necessary to identify the document and the following information: the date of disposal or transfer; the manner of disposal or transfer; the reason for disposal or transfer; the person authorizing the disposal or transfer; and the person disposing of or transferring the document.

19. If you claim the attorney-client privilege, or any other privilege or work product protection for any document, you shall provide the following information with respect to each such document:

a. the type of document;

b. general subject matter of the document;

c. date of the document; and

d. such other information as is sufficient to identify the document for a subpoena duces tecum, including, where appropriate, the author of the document, the addressee of the document, and, where not apparent, the relationship of the author and addressee to each other.

IV. DOCUMENT REQUESTS

1. Any and all documents regarding any Citizen Petition filed regarding leflunomide.

2. Any and all documents regarding, analyzing, or discussing the impact of the Aventis Citizen Petition regarding any generic versions of leflunomide, including, but not limited to, sales and launch projections, launch schedules, meeting minutes, emails, internal communications and press releases.

3. Any and all documents regarding actions, conduct, or strategies other than Citizen Petitions employed by Aventis, which delayed or prevented, or may have delayed or prevented, the introduction of generic Arava (leflunomide).

4. Any and all documents regarding your plans for launching leflunomide in any strength, including launch updates, timelines, schedules, asset allocation analysis, sales forecasts, and documentation regarding validation, scale up, and commercial production.

5. All documents relating to the actual and/or projected size, composition, dollar sales, and/or unit sales of the United States market(s) in which leflunomide products are sold.

6. Any and all documents regarding FDA regulatory approval of your ANDA for leflunomide, including but not limited to:

(a) your ANDA, including amendments and supplements;

(b) any and all correspondence with the FDA;

(c) any and all internal communications about your ANDA, including telephone contact reports;

(d) any and all Citizen Petitions;

(e) any Comment(s) to Citizen Petitions;

(f) any and all actual and draft labeling and discussions regarding same; and

(g) memorializations of communications from FDA concerning when your ANDA would be finally approved and the impediments, if any, to such final approval.

7. Any and all documents regarding the identification, development, approval, formulation, scale up, validation, manufacturing, and marketing of any leflunomide products, including but not limited to agendas and minutes of meetings of any product identification teams/committees, product development teams/committees, or any other teams, committees or departments involved in the aforementioned activities.

8. Any and all documents regarding communications with Aventis regarding Arava or any other leflunomide product.

9. All transaction-level sales (and sales adjustment) data (in digital, computer-readable format) relating to your sales of any leflunomide products. Such data shall identify, where applicable, for each sale and/or other transaction (including returns and error corrections):

(a) the date thereof, the identity of the particular product, and any and all codes relating to transaction types;

(b) the name and address of, and all unique codes or identifiers for, the person, firm, corporation, or other business entity whom you billed or credited for the sale (the "bill-to customer") and, in addition, the full name and address of the parent company, if the database or documents identify a subsidiary, corporate affiliate, division,

satellite office, or warehouse;

(c) the name and address of, and all unique codes or identifiers for, the person, firm, corporation, or other business entity to whom you shipped the products (the "ship-to customer") and, in addition, the full name and address of the parent company, if the database or documents identify a subsidiary, corporate affiliate, division, satellite office, or warehouse;

(d) the SKU, NDC, UPC, package size in extended units per package, and any and all other unique codes or other identifiers;

(e) the number of packages sold, returned or otherwise affected by the transaction;

(f) any price or unit adjustments (including but not limited to discounts, rebates, chargebacks, billbacks, price adjustments, shelf-stock price adjustments, returns, error corrections, free goods, and/or nominally-priced goods), whether monthly, quarterly or at any other periodicity, involving or relating to sales or transactions of leflunomide products, and including all database fields specified above in this request; and

(g) the net amount in dollars, dollars per package, and dollars per unit, for each sale or transaction and/or the source of the transaction price.

10. With regard to the data requested in the immediately-preceding Request, please

provide: (a) a separate product list, including NDC, SKU, UPC, product description, and package size; (b) a separate table that lists, for each "bill-to customer" and "ship-to customer," the customer number, parent customer number, customer group number, customer identity, contact information, address, and class of trade (*e.g.*, SIC code); (c) a separate table listing and defining each transaction code, abbreviation, or other field or entry code, and indicating whether quantity values for each transaction type should be included in calculating net quantity sold, or should be ignored because they do not affect net quantity sold; and (d) all datasets and calculations used (i) to determine accrued rebates and/or chargebacks and/or (ii) to periodically reconcile accrued rebates and/or chargebacks with actual rebates and/or chargebacks.

11. All data, in digital, computer-readable format, relating to chargebacks, rebates, discounts, and/or other consideration given and/or accrued relating to sales of leflunomide products. Such data shall identify:

(a) each transaction, including the date thereof;

(b) the name and address of, and all unique codes or identifiers for, the person, firm, corporation, or other business entity whom you paid, and/or on whose behalf you accrued, the chargeback, rebate, discount and/or other consideration;

(c) the name and address of, and all unique codes or identifiers for, the person(s), firm(s), corporation(s), or other business entity(ies) that made the purchase(s) in respect of which you paid and/or accrued the chargeback, rebate, discount and/or other consideration;

(d) the sales, or group of sales, upon which the rebate, discount and/or other

consideration is based, including:

(1) the number of units of the particular product sold, by package size, SKU, UPC, NDC, and any and all other unique codes or other identifiers for each sale or other transaction;

(2) the bill-to customer;

(3) the ship-to customer;

(4) the date(s) of the sales, or group of sales;

(5) the invoice amount in dollars for the sale(s) or group of sales;

(e) the amount of the chargeback, rebate, discount, and/or other consideration paid and/or accrued;

(f) the contract, agreement, or other basis upon which the chargeback, rebate, discount, and/or other consideration is calculated.

12. All documents which reflect the prices charged to, and other terms and/or conditions of sale of leflunomide products, including, but not limited, to:

(a) the wholesale acquisition cost, direct price, wholesale price, catalog price, list price, and every other published price;

(b) payment terms;

(c) discounts, rebates, chargebacks and/or other price and/or quantity adjustments offered to any purchaser, class of customer, and/or class of trade, including but not limited to wholesale purchasers, chain pharmacy purchasers, hospital

purchasers, managed care purchasers, mail order purchasers, and each and every type and/or class of purchaser or trade;

(d) pricing manuals, matrices, guidelines, policies, and/or formulas, for each customer, class of customer, and/or class of trade or subgroup thereof.

13. Documents sufficient to identify each person, firm, corporation and/or other business entity that purchased leflunomide products directly from you.

14. All documents constituting or relating to written contracts for the sale, in whole or in part, of leflunomide products by you. This Request includes, but is not limited to (i) contracts which generate chargebacks and (ii) contracts between you and a purchaser that provide that the purchaser will take delivery of leflunomide products from a person, firm, corporation and/or business entity other than you (such as a wholesaler).

15. All IMS data, in electronic format, relating to leflunomide products.

16. All other third-party documents and data (including from First DataBank, Medispan, PriceChek, Scott-Levin, ImpactRx, or any other similar entity) relating to leflunomide products.

17. All documents relating to analysis of, and/or projections and/or forecasts relating to, the market(s) in which leflunomide products are, or would be, sold. This includes, but is not limited to, documents relating to pricing, supply, demand, sales forecasts, sales, sales trends, sales projections, profit projections, output, output restrictions, output expansions and/or contractions, market share, product features, product benefits, manufacturing costs, other costs, budgeting, anticipated new entrants, contracting, distribution channels, and purchaser characteristics and/or behavior.

18. Any and all documents demonstrating, considering, discussing or embodying any proposed or actual marketing of your leflunomide products, including any and all communications with purchasers concerning the availability, or anticipated availability, of leflunomide products.

19. Documents sufficient to show your document destruction, retention and/or archiving policies and/or practices.

20. Organizational charts, personnel directories, telephone directories, and electronic mail user and address lists for you as a whole and for each division, subsidiary, or affiliate of the Company that had or has any involvement in the research, development, regulatory approval, manufacture, sale or marketing of Arava and/or any leflunomide product.

21. Any and all documents showing the effect or potential effect of the marketing of an AB-rated version of Arava on unit/dollar sales of Arava.

22. Any and all documents showing the effect or potential effect of the marketing of an AB-rated version of leflunomide on unit/dollar sales of other products in the same therapeutic class.

23. Any and all documents concerning the 100 mg leflunomide dosage strength, sometimes called the "loading dose," including but not limited to:

a. your decision to seek, or not seek, approval to market a generic version of leflunomide at the 100 mg dosage strength, and the bases therefore;

b. your licensing of the 100 mg dosage strength from any person, firm, or corporation;

c. the extent, if any, to which you were seeking an FDA determination that five (5) twenty-milligram leflunomide tablets were therapeutically equivalent to one (1) 100 mg tablets;

d. the patient population for which a 100 mg leflunomide tablet was unnecessary or contraindicated;

e. Aventis's reasons for making branded Arava in the 100 mg dosage strength available only as samples; and

f. The actual and/or proposed labeling of generic Arava mentioning the 100 mg dosage strength, and any communications with FDA in connection therewith.